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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,647	08/07/2001	Sean Adams	P1219P3	7392

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GENENTECH, INC.  
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EXAMINER

SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/17/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/924,647

Applicant(s)

ADAMS et al.

Examiner

Christine Saoud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-95 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
~~If approved, corrected drawings are required in reply to this Office action.~~

- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-21, drawn to polynucleotides, vectors, host cells and methods of making a polypeptide, classified in class 435, subclass 69.4, for example.
  - II. Claims 22-31, 38 drawn to a polypeptide, classified in class 530, subclass 350, for example.
  - III. Claims 32-35, 38, drawn to an antibody to a polypeptide, classified in class 530, subclass 387.1, for example.
  - IV. Claims 36 and 38, drawn to a compound of unspecified constitution (identified as an agonist), class undeterminable, subclass undeterminable.
  - V. Claims 37 and 38, drawn to a compound of unspecified constitution (identified as an antagonist), class undeterminable, subclass undeterminable.
  - VI. Claim 39, drawn to a method of screening for a binding agent (using the polypeptide), class 436, subclass 501, for example.
  - VII. Claims 40-43, drawn to a method of screening for modulation of activity (using the polypeptide), classified in class 435, subclass 4, for example.

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  - VIII. Claims 44-47, drawn to a method of identifying a receptor (using the polypeptide), classified in class 436, subclass 501, for example.
  - IX. Claims 48-49, drawn to a method of inducing leptin release (using the polypeptide), classified in class 514, subclass 2, for example.
  - X. Claims 48, 50, drawn to a method of inducing leptin release (using the polynucleotide), classified in class 514, subclass 44, for example.
  - XI. Claims 51-52, drawn to a method of inducing a decrease in glucose uptake (using the polypeptide), classified in class 514, subclass 2, for example.
  - XII. Claims 51, 53, drawn to a method of inducing a decrease in glucose uptake (using the polynucleotide), classified in class 514, subclass 44, for example.

- XIII. Claims 54-55, drawn to a method of increasing insulin sensitivity (using the polypeptide), classified in class 514, subclass 2, for example.
  - XIV. Claims 54, 56, drawn to a method of increasing insulin sensitivity (using the polynucleotide), classified in class 514, subclass 44, for example.
  - XV. Claims 57-60, 62-63, drawn to a method of treating obesity (using the polypeptide), classified in class 514, subclass 2, for example.
  - XVI. Claims 57, 61-61, drawn to a method of treating obesity (using the polynucleotide), classified in class 514, subclass 44, for example.
  - XVII. Claims 64-65, 67 drawn to a method of reducing body mass (using the polypeptide), classified in class 514, subclass 2, for example.
  - XVIII. Claims 64, 66-67, drawn to a method of reducing body mass (using the polynucleotide), classified in class 514, subclass 44, for example.
  - XIX. Claims 70-71, 73-74 drawn to a method of reducing triglycerides (using the polypeptide), classified in class 514, subclass 2, for example.
  - XX. Claims 70, 72-73, drawn to a method of reducing triglycerides (using the polynucleotide), classified in class 514, subclass 44, for example.
  - XXI. Claims 75-76, 78-79, drawn to a method of increasing metabolic rate (using the polypeptide), classified in class 514, subclass 2, for example.
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- XXII. Claims 75, 77-78, drawn to a method of increasing metabolic rate (using the polynucleotide), classified in class 514, subclass 44, for example.
  - XXIII. Claim 80, drawn to a transgenic animal, classified in class 800, subclass 2.
  - XXIV. Claims 81-82, 84-85, drawn to a method of modulating the level of neuropeptide Y (using the polypeptide), classified in class 514, subclass 2, for example.
  - XXV. Claims 81, 83-85, drawn to a method of of modulating the level of neuropeptide Y (using the polynucleotide), classified in class 514, subclass 44, for example.
  - XXVI. Claims 86-87, 89-90, drawn to a method of modulating the level of agouti-related protein (using the polypeptide), classified in class 514, subclass 2, for example.

XXVII. Claims 86, 87-90, drawn to a method of modulating the level of agouti-related protein (using the polynucleotide), classified in class 514, subclass 44, for example.

XXVIII. Claims 91-92, 94-95, drawn to a method of modulating the level of pro-opiomelanocortin (using the polypeptide), classified in class 514, subclass 2, for example.

XXIX. Claims 91, 93-95, drawn to a method of modulating the level of pro-opiomelanocortin (using the polynucleotide), classified in class 514, subclass 44, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I could be used in an entirely different method, such as in a method of detection of the polynucleotide in a sample, rather than in a method of making the polypeptide.

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4. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II could be used for an entirely different purpose such as in a method of treatment, rather than for the production of antibodies of Group III.

5. Inventions I-V, XXIII are also unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to chemically different compounds or products which can be made and used without each other. Furthermore, the inventions of Groups I-V, XXI lack a common utility which is based upon a common special technical feature which is disclosed as being responsible for the common utility.

6. Inventions I and (X, XII, XIV, XVI, XVIII, XX, XXII, XXIII, XXV, XXVII, XXIX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I could be used in an entirely different manner, such as in a method of making the polypeptide rather than in the methods of Groups (X, XII, XIV, XVI, XVIII, XX,

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XXII, XXIII, XXV, XXVII, XXIX).

7. Inventions I and (VI-IX, XI, XIII, XV, XVII, XIX, XXI, XXIV, XXVI, XXVIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polynucleotide of Group I is not required for any of the methods of Groups (VI-IX, XI, XIII, XV, XVII, XIX, XXI, XXIV, XXVI, XXVIII).

8. Inventions II and (VI-IX, XI, XIII, XV, XVII, XIX, XXI, XXIV, XXVI, XXVIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group II could be used in an entirely different manner, such as in a method of making antibodies rather than in the methods of Groups (VI-IX, XI, XIII, XV, XVII, XIX, XXI, XXIV, XXVI, XXVIII).

9. Inventions II and (X, XII, XIV, XVI, XVIII, XX, XXII, XXIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polypeptide of Group II is not required for any of the methods of Groups (X, XII, XIV, XVI, XVIII, XX, XXII, XXIII, XXV, XXVII, XXIX).

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10. Inventions (III-V) and (VI-XXIII) are unrelated, respectively. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that none of the compounds of Groups III-V are required for the methods of Groups VI-XXIX.

11. Inventions VI-XXIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods which have different method steps, starting materials and goals.

12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the ~~inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently~~ named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The Examiner can normally be reached on Monday to Thursday from 8AM to 2PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.



Application/Control Number: 09/924,647  
Art Unit: 1647

Page 8

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §§ 1.6(d) and 1.8). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternate number. Official papers filed After Final rejection filed by fax should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CHRISTINE J. SAUD  
PRIMARY EXAMINER

*Christine J. Saud*

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